

STATE OF MAINE

IN THE YEAR OF OUR LORD
TWO THOUSAND AND THIRTEEN

S.P. 395 - L.D. 1134

**An Act To Allow Collaborative Practice Agreements between Authorized
Practitioners and Pharmacists**

Be it enacted by the People of the State of Maine as follows:

Sec. 1. 32 MRSA §13702-A, sub-§§2-A and 2-B are enacted to read:

2-A. Collaborative drug therapy management. "Collaborative drug therapy management" means the initiating, monitoring, modifying and discontinuing of a patient's drug therapy by a pharmacist as authorized by a practitioner in accordance with a collaborative practice agreement. "Collaborative drug therapy management" includes collecting and reviewing patient histories; obtaining and checking vital signs, including pulse, temperature, blood pressure and respiration; and, under the supervision of, or in direct consultation with, a practitioner, ordering and evaluating the results of laboratory tests directly related to drug therapy when performed in accordance with approved protocols applicable to the practice setting and when the evaluation does not include a diagnostic component.

2-B. Collaborative practice agreement. "Collaborative practice agreement" means a written and signed agreement between one or more pharmacists with training and experience relevant to the scope of the collaborative practice and a practitioner that supervises or provides direct consultation to the pharmacist or pharmacists engaging in collaborative drug therapy management that:

A. Defines the collaborative practice, which must be within the scope of the supervising practitioner's practice, in which the pharmacist or pharmacists may engage;

B. States the beginning and ending dates of the period of time during which the agreement is in effect; and

C. Includes individually developed guidelines for the prescriptive practice of the participating pharmacist or pharmacists.

Sec. 2. 32 MRSA §13702-A, sub-§28, as amended by PL 2011, c. 577, §1, is further amended to read:

28. Practice of pharmacy. "Practice of pharmacy" means the interpretation and evaluation of prescription drug orders; the compounding, dispensing and labeling of drugs and devices, except labeling by a manufacturer, packer or distributor of nonprescription drugs and commercially packaged legend drugs and devices; the participation in drug selection and drug utilization reviews; the proper and safe storage of drugs and devices and the maintenance of proper records for these drugs and devices; the administration of vaccines licensed by the United States Food and Drug Administration that are recommended by the United States Centers for Disease Control and Prevention Advisory Committee on Immunization Practices, or successor organization, for administration to adults; the performance of collaborative drug therapy management; the responsibility for advising, when necessary or regulated, of therapeutic values, content, hazards and use of drugs and devices; and the offering or performing of those acts, services, operations or transactions necessary in the conduct, operation, management and control of a pharmacy.

Sec. 3. 32 MRSA §13735, first ¶, as amended by PL 2009, c. 308, §2, is further amended to read:

An annual renewal license may not be issued by the board until the applicant certifies to the board that, during the calendar year preceding an application for renewal, the applicant has participated in not less than 15 hours of approved courses of continuing professional pharmaceutical education as set out in this section. Of the 15 hours to be completed, at least 2 hours must be in board-approved courses on drug administration as described in section 13702-A, subsection 28. A pharmacist who enters into a collaborative practice agreement must agree to complete, in each year of the agreement, 5 of the 15 hours required in this section in the areas of practice covered by the agreement. The continuing professional pharmaceutical educational courses consist of postgraduate studies, institutes, seminars, workshops, lectures, conferences, extension studies, correspondence courses or such other forms of continuing professional pharmaceutical education as may be approved by the board.

Sec. 4. 32 MRSA c. 117, sub-c. 14 is enacted to read:

SUBCHAPTER 14

COLLABORATIVE DRUG THERAPY MANAGEMENT

§13841. Authority

1. Engage in collaborative drug therapy management. A pharmacist licensed in this State who meets the qualifications and requirements of section 13842 and rules adopted by the board may engage in collaborative drug therapy management pursuant to a collaborative practice agreement with a practitioner.

2. Scope of authority. A pharmacist engaging in collaborative drug therapy management pursuant to subsection 1 is entitled to adequate access to a patient's history, disease status, drug therapy and laboratory and procedure results and may:

- A. Collect and review a patient's history;
- B. Obtain and check vital signs;
- C. Order and evaluate the results of laboratory tests directly related to drug therapy under the supervision of, or in direct consultation with, a practitioner and in accordance with approved protocols applicable to the practice setting and when the evaluation does not include a diagnostic component; and
- D. Initiate, monitor, modify and discontinue drug therapy for a particular patient pursuant to the collaborative practice agreement with a practitioner who is treating the patient, as long as the action is reported to the practitioner in a timely manner as determined by rules adopted pursuant to section 13846.

§13842. Qualifications

In order to enter into a collaborative practice agreement with a practitioner under this subchapter, a pharmacist must:

1. License. Hold a valid unrestricted pharmacist license in this State;

2. Training. Submit evidence acceptable to the board that the pharmacist:

A. Possesses certification from the Board of Pharmacy Specialties or successor organization or has completed an accredited residency program. If the residency program is not in the area of practice covered by the agreement, the pharmacist must complete a continuing education certificate program of at least 15 hours of continuing education in each clinical area of practice covered by the agreement;

B. Has graduated with a Doctor of Pharmacy degree from a college of pharmacy accredited by the American Council on Pharmaceutical Education, has 2 years of professional experience and has completed a continuing education certificate program of at least 15 hours of continuing education in each clinical area of practice covered by the agreement; or

C. Has graduated with a Bachelor of Science in Pharmacy degree from a college of pharmacy accredited by the American Council on Pharmaceutical Education, has 3 years of professional experience and has completed a continuing education certificate program of at least 15 hours of continuing education in each clinical area of practice covered by the agreement.

§13843. Collaborative practice agreement

A pharmacist may engage in collaborative drug therapy management pursuant to a collaborative practice agreement in accordance with this section.

1. Submit to board. The pharmacist shall submit a copy of the collaborative practice agreement to the board and the licensing board that licenses the practitioner prior to the commencement of the collaborative practice.

2. Review and revision. The signatories to a collaborative practice agreement shall establish a procedure for reviewing and, if necessary, revising the procedures and protocols of the collaborative practice agreement.

3. Health information privacy. Services provided pursuant to a collaborative practice agreement must be performed in compliance with the federal Health Insurance Portability and Accountability Act of 1996, 42 United States Code, Section 1320d et seq. and its regulations, 45 Code of Federal Regulations, Parts 160-164.

4. Amendments to agreement. Amendments to a collaborative practice agreement must be documented, signed and dated.

5. Assessment; risk management. A collaborative practice agreement must include a plan for measuring and assessing patient outcomes and must include proof that liability insurance is maintained by all parties to the agreement.

6. Contents of agreement. A practitioner and a pharmacist desiring to engage in collaborative practice in accordance with this subchapter shall execute a collaborative practice agreement that must contain, but is not limited to:

A. A provision that states that activity in the initial 3 months of a collaborative practice agreement is limited to monitoring drug therapy. After the initial 3 months, the practitioner and pharmacist shall meet to review the collaborative practice agreement and determine the scope of the agreement, which may after the initial 3 months include a pharmacist's initiating, monitoring, modifying and discontinuing a patient's drug therapy and reporting these actions to the practitioner in a timely manner in accordance with rules adopted pursuant to section 13846;

B. Identification and signatures of the parties to the collaborative practice agreement, the dates the agreement is signed and the beginning and ending dates of the period of time during which the agreement is in effect;

C. A provision that allows either party to cancel the collaborative practice agreement by written notification;

D. Specification of the site and setting at which the collaborative practice will occur;

E. Specification of the qualifications of the participants in the collaborative practice agreement;

F. A detailed description of the types of diseases, drugs or drug categories involved and collaborative drug therapy management allowed in each patient's case; and

G. A procedure for the referral of each patient to the practitioner.

§13844. Conditions or diseases managed; scope of practice

1. Generally accepted standards of care. A pharmacist may engage in collaborative drug therapy management pursuant to a collaborative practice agreement only for conditions or diseases with generally accepted standards of care.

2. Prohibition. A pharmacist who is engaged in collaborative drug therapy management pursuant to a collaborative practice agreement may not, as part of the collaborative practice, participate in research or clinical or investigational trials.

3. Limitation. A collaborative practice agreement may include only the conditions or diseases to be managed that meet the qualifications and scope of practice for each party to the agreement.

§13845. Practice protocols

A pharmacist may engage in collaborative drug therapy management in compliance with a treatment protocol established by the practitioner with whom the pharmacist has a collaborative practice agreement. A copy of the treatment protocol must be submitted to the board. At a minimum, the treatment protocol must include a statement by the practitioner that describes the activities in which the pharmacist is authorized to engage and a provision that allows the practitioner, when appropriate, to override a collaborative practice decision made by the pharmacist.

§13846. Rules

The board and the Board of Licensure in Medicine, after consultation with the Department of Health and Human Services, shall adopt rules to implement this subchapter. The rules must include rules establishing record-keeping and documentation procedures and reporting requirements and must allow for electronic filing when possible. Rules adopted pursuant to this section are routine technical rules as defined in Title 5, chapter 375, subchapter 2-A.

§13847. Exemptions

Nothing in this subchapter may be construed to limit the scope of practice of a pharmacist pursuant to this chapter or to apply to collaborative practice agreements entered into between a pharmacist and a hospital solely for the treatment of inpatients at the hospital.